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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/696,362

10/30/2003

Edward W. Merrill

00952-8081

6751

61263 7590 09/14/2009

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EXAMINER

BERMAN, SUSAN W

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

09/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/696,362	Applicant(s) MERRILL ET AL.	
	Examiner /Susan W. Berman/	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-129 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124-129 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08-26-2009 has been entered.

Response to Arguments

Applicant's arguments filed 08-26-2009 have been fully considered but they are not persuasive. See the previous discussions of these issues in the Office Actions mailed 1/14/2007, 09-07-2007, 12-12-2006 and 07-24-2008.

In response to applicant's argument that the examiner's position has not been consistent, it is reiterated that claims 127-129 do not recite any specific order of steps and thus encompass heating before irradiation and irradiation before heating. There is no requirement that instant claims 127-129 specify the order of heating and irradiation since applicant discloses methods wherein heating precedes irradiation and methods wherein irradiation precedes heating. However, in the instant case, the prior art rejections stand because claims 127-129, as written, can be interpreted as reciting a method of heating before irradiation (Dijkstra et al) and also as reciting a method of irradiation before heating (Hyon et al). The claims are anticipated by Hyon et al because the filing date of patent 6,168,626 is earlier than applicant's effective filing date with respect to a process wherein irradiation is followed by heating the irradiation UHMWPE.

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The instant claims do not recite more than one heating and/or irradiation step or simultaneous heating and irradiation. Applicant again argues that cooling during the pause in between passes or irradiation and continued heating are inherent in the process set forth in the instant claims. This argument is not persuasive because nothing in the disclosure of the instantly claimed method in the specification mentions that there are pauses in between passes or irradiation or that the material is cooled and then reheated during the process for irradiating the UHMWPE. There is no evidence of record to support the allegation that the argued process is clear to one skilled in the art. A reduction to practice, as evidenced in the Rule 1.131 Declaration of Merrill et al filed 06-08-2007 wherein polyethylene is first melted and then irradiated is not evidence of reduction to practice of a method wherein irradiation is followed by subsequent melting. Furthermore, this argument is irrelevant to the instant claims because the instant claims do not mention or require more than one heating and/or irradiation step

The rejection of claims 124-129 under 35 U.S.C. 102(b) as being anticipated by Dijkstra et al, in the article "Crosslinking of Ultra-high Molecular Weight Polyethylene in the Melt by Means of Electron Beam Irradiation" published May, 1989 is maintained. Applicant's arguments have been fully addressed in previous office actions. No new arguments have been presented in the Remarks filed 08-26-2009.

The rejection of claims 127-129 under 35 U.S.C. 102(b) as being anticipated by Hyon et al (6,168,626) is maintained. This rejection is maintained wherein the claims are interpreted as reciting a process wherein the UHMWPE perform is first irradiated and the heated to the recited temperature. This interpretation of the claimed process has an effective filing date of 10-02-1996, which is before the filing date of patent 6,168,626 to Hyon et al. As previously established,

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the Rule 1.131 Declaration of Merrill et al filed 06-08-2007 wherein polyethylene is first melted and then irradiated is not evidence of reduction to practice of the method wherein irradiation is followed by subsequent melting that is encompassed by the claims as written.

With respect to applicant's intent to provoke an interference with Patent 6,316,158 to Saum et al, applicant has not presented allowable claims, therefor, an interference cannot be declared.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

It is noted that instant claims 124-126 are entitled to the 02-13-1996 filing date of US 5,879,400 because this parent patent discloses the method of melt irradiation (MIR). The instant claim language in 127-129 sets forth the IR-SM processes first disclosed in SN 08/726,313, but not disclosed in US '400, and also encompasses the MIR process disclosed in US '400. Therefore, the effective filing date for instant claims 127-129 is considered to be 10-02-1996, the filing date of application SN 08/726,313, which discloses WIR-SM and CIR-SM methods as well as the "MIR" method.

Claims 124-129 are rejected under 35 U.S.C. 102(b) as being anticipated by Dijkstra et al, in the article "Crosslinking of Ultra-high Molecular Weight Polyethylene in the Melt by Means of Electron Beam Irradiation" published May, 1989. Dijkstra et al disclose a process for crosslinking UHMWPE in the melt comprising heating a preform in a nitrogen atmosphere at

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200 °C and crosslinking with electron beams. See “experimental” on page 866, Table 1. With respect to claims 124-126, Dijkstra et al clearly teach heating to a temperature above the melting point of the UHMWPE to about 230°C, since 200°C is specifically taught. With respect to claims 127-129, the claims can be interpreted as requiring irradiating the perform after heating the perform. Therefor, Dijkstra et al anticipate the process set forth in claims 127-129 wherein the heating is performed before the irradiation. Since Dijkstra et al disclose process steps corresponding to those set forth in the instant claims, the process steps would be expected to provide a perform from which bearings having improved mechanical properties and increased wear resistance are to be fabricated, as set forth in the instant claims to define the future intended use of the process of treating the preform.

Claims 127-129 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (6,168,626, having an effective filing date of May 06, 1996). Hyon et al disclose a method for producing UHMWPE for an artificial joint comprising irradiating UHMWPE with a low dose of radiation followed by compression-deformation after melting at a high temperature around the melting point and then cooling and solidifying. Table 2 appears to show that the samples treated according to the disclosed process have an increased tensile strength and an increased Young's modulus. With respect to claim 128, Hyon et al disclose temperatures around or not less than the melting point, preferably 160-220 °C (column 4, lines 4-16). Thus, claim 128 is anticipated by the teaching of Hyon et al to employ a temperature from the melting point minus 50°C to the melting point plus 80°C, which temperatures, including 160-220°C preferred by Hyon et al, would be within the range of 145 to 300°C set forth in the claim. With respect to claim 129,

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Hyon et al teach a preferable dose 0.01 to 5.0 MR (column 3, lines 62-65). Thus the process disclosed by Hyon et al anticipates the process of instant claim 129 wherein the gamma radiation dose is about 1 Mrad to 5.0 Mrad.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129, 131-134 of copending parent Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the processes set forth in the corresponding claims overlap wherein the heating is at a temperature above the melting point to about 300⁰C and the time period is from about 5 minutes to about 3 hours or a time period of 5 minutes to about 24 hours and the polyethylene is UHMWPE. The processes set forth in the dependent claims also overlap with respect to temperature, radiation dose and intended

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properties. Thus the limitations of the process set forth in the instant claims are obvious variants of the limitations set forth in the claims of A.N. 10/197209.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-125, 130 and 143-146 of copending parent Application No. 09/764,445. Although the conflicting claims are not identical, they are not patentably distinct from each other because the processes set forth in the corresponding claims overlap wherein the heating is at a temperature above the melting point and below the decomposition temperature for a time period from about 5 minutes to about 3 hours. The processes set forth in the dependent claims also overlap with respect to temperature, radiation dose and intended properties. The polyethylene recited in the claims of A.N. '445 encompasses the UHMWPE recited in the instant claims. Claims 124, 125 and 130 suggest instant claim 127. Claim 143 suggests instant claim 124. Thus species within the instant claims are obvious from the limitations set forth in the claims of A.N. 09/764,445.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
9/10/2009

/Susan W Berman/
Primary Examiner
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